PCT/AU03/00807

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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PS 3355 for a patent by USCOM PTY LTD as filed on 03 July 2002.

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Seventh day of July 2003

J. Billingsley

JULIE BILLINGSLEY
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AUSTRALIA

PATENTS ACT 1990

PROVISIONAL SPECIFICATION

FOR THE INVENTION ENTITLED:-

"PACEMAKER EVALUATION METHOD AND APPARATUS"

The invention is described in the following statement:-

PACEMAKER EVALUATION METHOD AND APPARATUS

FIELD OF THE INVENTION

The present invention relates to the field of cardiac pacemakers and, in particular, discloses a methodology and apparatus for selectively tuning a pacemaker-type device.

BACKGROUND OF THE INVENTION

Pacemaker devices normally consist of the pacemaker control unit containing a power cell such as a battery, a pacemaker lead and an end electrodes which are attached to the heart so as to stimulate the heart into action at certain timed occurrences. Recent advances in pacemaker technology include providing for fully programmable capabilities. Modern pacemaker devices often include on board processing and storage capabilities and the latest models allow for external communication with reader and control devices located outside the body for telecommunications..

Modern pacemaker devices also allow for a variability in operation of the heart in accordance with external needs. For example, during exercise, the pacemaker device may increase the heart rate. Further, during periods of rest the pacemaker device need decrease the heart rate. Further, programmable pacemakers allow for storage of information for downloading as to the onboard operation of the pacemaker unit.

There is therefore a general need to accurately and succinctly tune the pacemaker unit for the proper operation of the heart muscle.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide for a method and apparatus for tuning the operation of pacemaker units to achieve more optimal results.

In accordance with a first aspect of the present invention, there is provided a method of tuning a cardiac prosthetic pacing device, the method comprising the steps of (a) monitoring the flow output from the heart; and (b) adjusting the timing of pacing events by the cardiac prosthetic pacing device so as to optimise the flow from the heart under operational conditions.

Preferably, the method includes monitoring the flow utilising a continuous wave Doppler signal directed at the heart. Ideally, the method is repeated under a number of different operational conditions for a patient including walking and/or running. Further,

preferably the method is repeated under a number of different pharmalogical conditions for a patient.

In accordance with a further aspect of the present invention, there is provided an apparatus for tuning a cardiac prosthetic pacing device, the apparatus including: monitoring means for non invasively monitoring the flow of blood out of the heart; control means for controlling the operation of the cardiac prosthetic pacing device including variation of the pacing rate; and processing means interconnected to the monitoring means and the control means, the processing means instructing the control means to vary the pacing rate of the cardiac prosthetic pacing device and monitor the corresponding measurement of the monitoring means.

Preferably, the monitoring means includes a continuous wave Doppler sensor device for emitting and receiving a CW- Doppler signal at a patients heart.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention will now be described with reference , by way of example only, with reference to the accompanying drawings in which:

Fig. 1 illustrates a first operational environment of the preferred embodiment;

Fig. 2 illustrates a sectional view through a transducer device;

Fig. 3 illustrates a velocity time snapshot as measured by the CW transducer device;

Fig. 4 illustrates various portions of the snapshot of Fig. 3;

Fig. 5 illustrates the steps involved in optimising the pacemaker arrangement of the preferred embodiment.

DESCRIPTION OF PREFERRED AND OTHER EMBODIMENTS

In the preferred embodiment, continuous wave ultrasound techniques are utilised to measure the cardiac output of a heart operating with a cardiac prosthetic pacing device. Through utilisation of ultrasound techniques, a measurement of cardiac output can be obtained as a function of rate and volume. The ultrasound techniques also provide a measure of stroke volume thereby providing information for optimisation of settings on the pacemakers.

Turning initially to Fig. 1, there is illustrated one arrangement utilising the preferred embodiment. In this arrangement, a patient 10 has attached two non-invasive monitoring devices 11-13. Each of the two devices 11-13 are interconnected to a

processing and display unit eg. 12, 14. Each of the units 12, 14 includes an internal computer processing means, a display and a series of control buttons for controlling the functionality of the device. Each of the devices 12, 14 are further networked to a base station or the like for overall monitoring and control.

The sensor 13 is in telemetry connection with the heart pacemaker unit. It is assumed that the device 14 in conjunction with sensor 13 is able to vary the rate at which the heart paces. Hence, variations in blood flow around the body can be measured by alteration of the heart pacemaker timing period whilst simultaneously monitoring the corresponding alteration in blood flows as detected by the CW transducer device. In this manner the pacing period can be optimised for the particular receipeint by estimation of the flow requirements of the recepient given their size, weight etc.

Fig. 2 shows an example of the first actuator 11 for attachment to the skin surface. Ideally CW Doppler is utilised to monitor the blood flow within the heart. CW Doppler is a non-invasive technique in which ultrasonic signals from transducer elements are directed into a blood carrying vessel of a patient. Doppler shifts in the reflected signal provide an indication of the rate of blood flow. In Fig. 2, a transducer element 11 includes an ultrasonic transducer 15 attached to a positioning device 16 which can be used to initially set the position of the transducer. Between the transducer 15 and a patient's skin 17 is placed a gel coupling layer 18 for coupling the ultrasonic transducer vibrations to the skin 17. The principles of CW Doppler flow measurement are known and do not themselves form part of the present invention. Patent Cooperation Treaty (PCT) publication number WO 99/66835 to the present assignee, the contents of which are incorporated herein by cross-reference, describes in more detail an ultrasonic transducer device suitable for measuring blood flow using the CW Doppler method. In the embodiment shown in Fig. 1, the transducer elements are placed on the patient to obtain intra-cardiac or aortic signals, for example through a suprasternal notch.

The CW method detects the velocity of individual blood cells by measuring the frequency change of a reflected ultrasound beam and displaying this as a time velocity flow profile, an example of which is shown in Fig. 3. The transducer output forms an input to the processor unit which image processes the results of Fig. 3 so as to calculate from the time velocity flow profile, the time velocity integral (tvi) and other relevant information such as heart rate (HR) and peak volume Vpk. These calculations can then

be compared with the pacemaker timing setting to determine an overall optimal performance.

The arrangement of Fig. 1 can then be translated into other real life situations. For example, on a walking treadmill and a running treadmill. Again, measurements can be taken of variation in blood flow pumping rates with variation in heart rates so as to thereby tune the operation of the pacemaker unit for the particular individual.

A flow chart of the overall steps involved in the operation of the preferred embodiment is illustrated generally 30 in Fig. 5. These include the steps of obtaining a CW Doppler flow measurement 31 and simultaneously obtaining pacemaker rate measurements 32. Next, a determination is made as to whether to increase or decrease the pacemaker rate measurement 33. Upon increasing or decreasing measurements, continual analysis of the change in flow rate is made 34.

Through the utilisation of flow measurements via the CW technique, advanced analysis can also be conducted. Normally, pacemakers are designed to regulate cardiac output by controlling the timing of events in the cardiac cycle and are usually set according to ECG criteria. ECG devices however measure only the heart rate and make no measure of cardiac output, a function of rate and volume, which is a measure of how much the heart pumps. The CW method provides a measure of the heart rate and total volume the heart pumps thereby providing more information required for optimisation of the settings of pacemaker devices. Obviously, testing in accordance with a wide variety of physiologic (exercise) conditions or pharmacologic testing is desirable.

By carrying out a large number of tests on a large number of patients various indicies can be built up in guiding the system in setting the pacing rates for particular patient activities. The test can be carried out on a plurality of patients and the total set of results statistically combined, e.g. averaged for patient variables such as age, sex, weight etc.

Additionally, the invention as described herein can be used to improve understanding of the normal physiology and pathophysiology associated with cardiovascular function, exercise and pulmonary function.

It will be understood that the invention disclosed and defined herein extends to all alternative combinations of two or more of the individual features mentioned or evident from the text or drawings. All of these different combinations constitute various alternative aspects of the invention.

The foregoing describes embodiments of the present invention and modifications, obvious to those skilled in the art can be made thereto, without departing from the scope of the present invention.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A method of tuning a cardiac prosthetic pacing device, the method comprising the steps of:

(a) monitoring the flow output from the heart;

(b) adjusting the timing of pacing events by said cardiac prosthetic pacing device so as to optimise the flow from the heart under operational conditions.

2. A method as claimed in claim 1 wherein said step (a) further comprises the step of monitoring the flow utilising a continuous wave Doppler signal directed at the heart.

3. A method as claimed in claim 1 wherein said method is repeated under a number of different operational conditions for a patient including walking and/or running.

4. A method as claimed in claim 1 wherein said method is repeated under a number of different pharmalogical conditions for a patient.

5. An apparatus for tuning a cardiac prosthetic pacing device, the apparatus including:

monitoring means for non invasively monitoring the flow of blood out of the heart;

control means for controlling the operation of the cardiac prosthetic pacing device including variation of the pacing rate;

processing means interconnected to said monitoring means and said control means, said processing means instructing said control means to vary the pacing rate of said cardiac prosthetic pacing device and monitor the corresponding measurement of said monitoring means.

6. An apparatus as claimed in claim 5 wherein said monitoring means includes a continuous wave Doppler sensor device for emitting and receiving a CW- Doppler signal at a patients heart.

7. A method for tuning a cardiac prosthetic pacing device substantially as hereinbefore described with reference to the accompanying drawings.

8. An apparatus for tuning a cardiac prosthetic pacing device substantially as hereinbefore described with reference to the accompanying drawings.

DATED this 3rd day of July, 2002

USCOM PTY LTD

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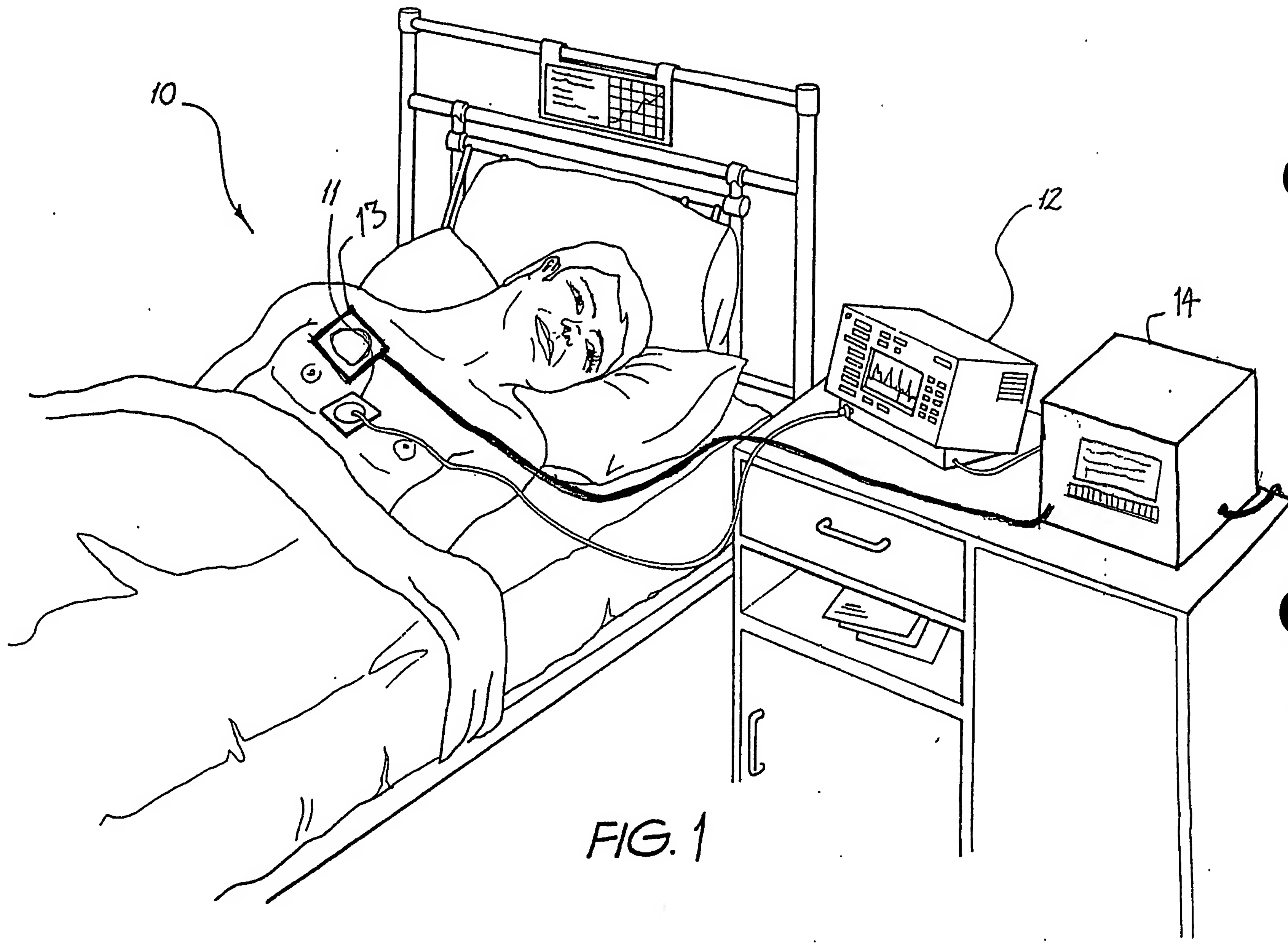


FIG. 1

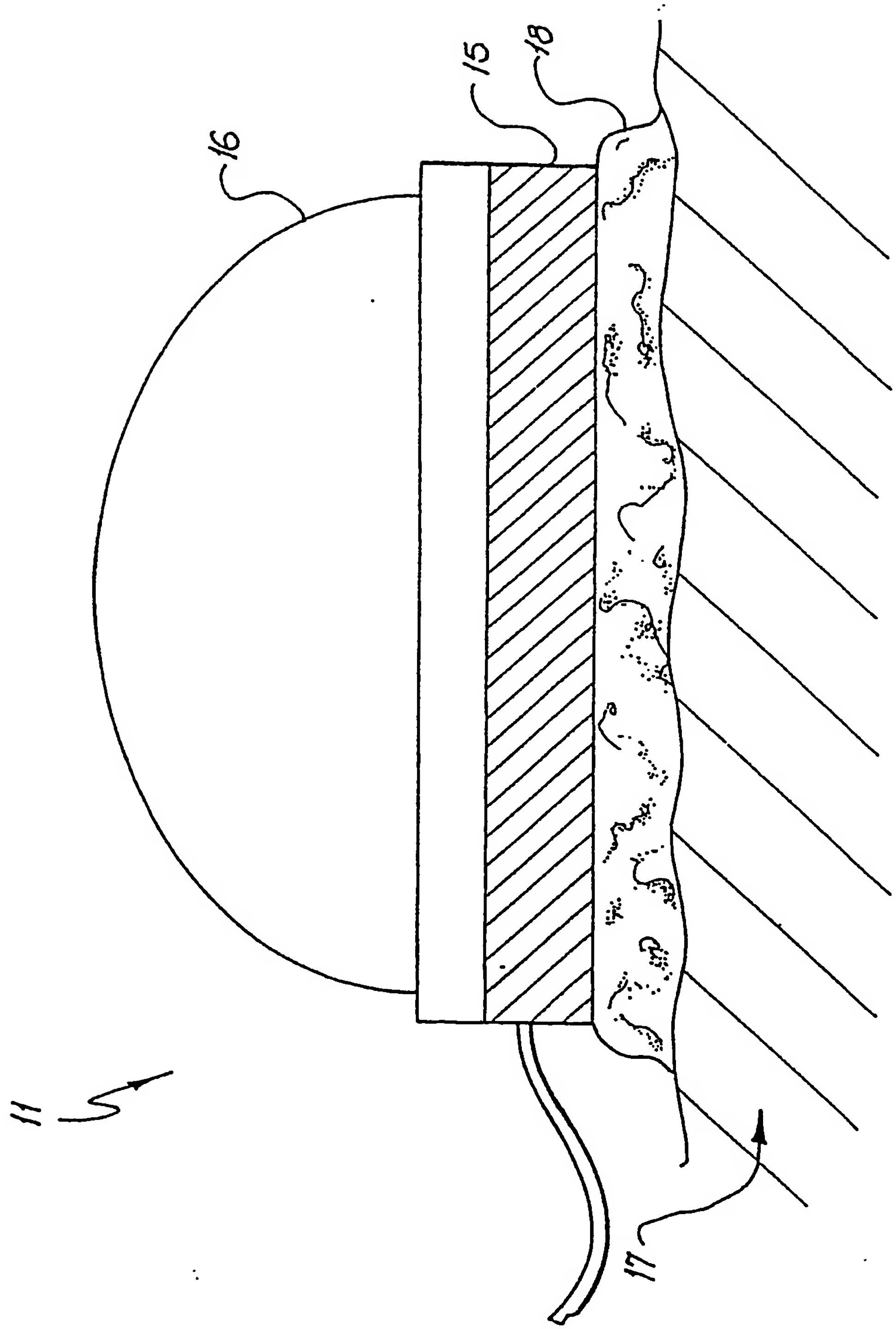
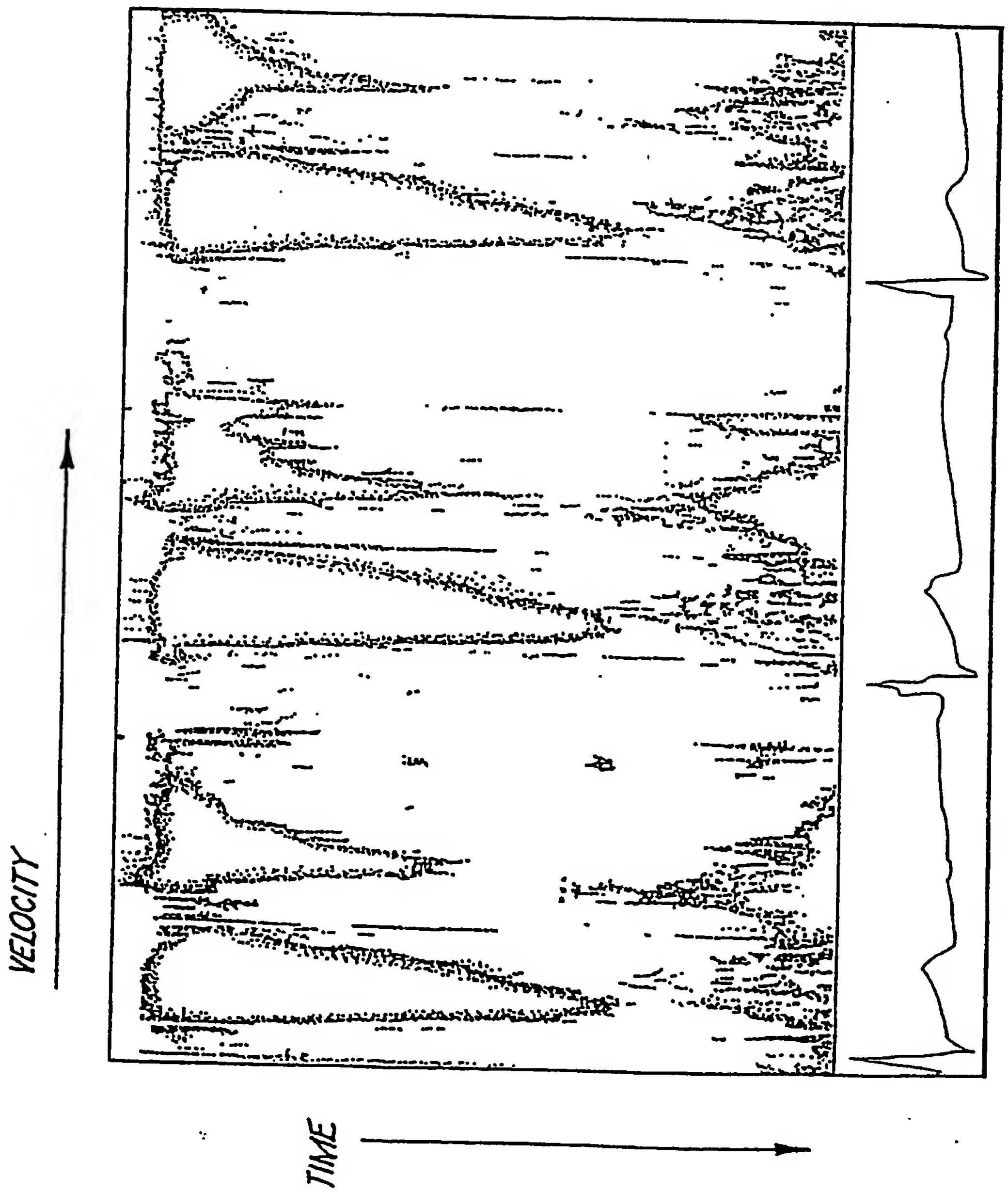


FIG 2

FIG. 3



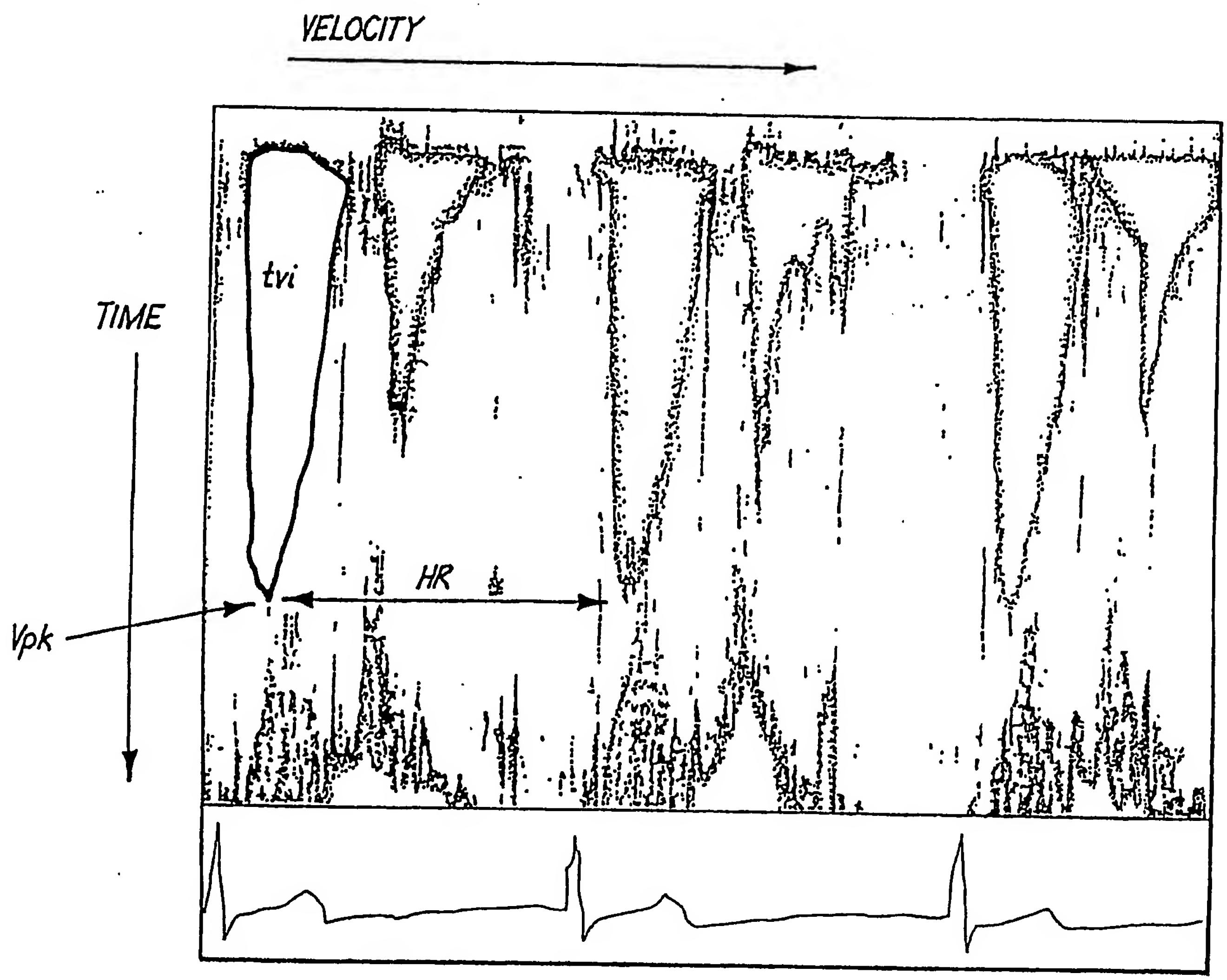


FIG. 4

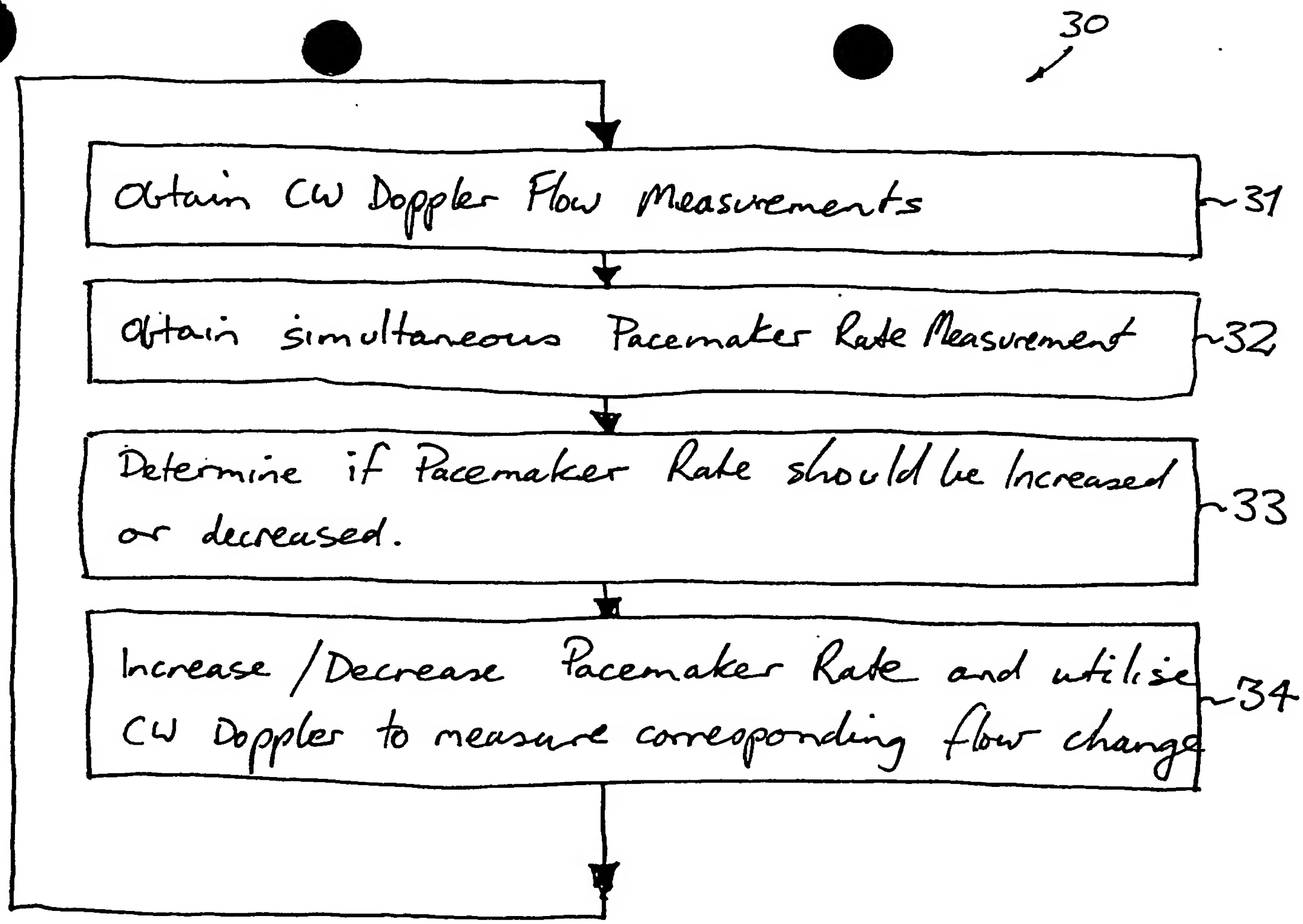

30
Obtain CW Doppler Flow Measurements
31
Obtain simultaneous Pacemaker Rate Measurement
32
Determine if Pacemaker Rate should be Increased or decreased.
33
Increase /Decrease Pacemaker Rate and utilise CW Doppler to measure corresponding flow change
34

Fig. 5